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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,458	03/17/2004	Patrick Fogarty	TOSK-006CON	5491

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EXAMINER

SIMMONS, CHRIS E

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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10/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,458	Applicant(s) FOGARTY, PATRICK	
	Examiner Chris E. Simmons	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims: Receipt of the amendments filed on 07/23/2007 is acknowledged. Claims 1-8 and 17-24 are currently amended. Claims 9-16 and 25-27 are currently canceled. Claims 1-8 and 17-24 are presented for examination.

Applicants' arguments, filed 07/23/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

RESPONSE TO ARGUMENTS

Regarding amended claim 17 which reads,

"A method of treating ovarian cancer in a patient, said method comprising: administering to said patient an amount of cisplatin effective to treat said cancer in conjunction with an amount of TK-211 effective to • reduce toxicity of said cisplatin. ",

Applicant argues "this compound has been shown effective in reducing the toxicity of cisplatin in human ovarian cancer cells, according to page 17, lines 24 and 28.

Accordingly, one of ordinary skill in the art is able to use the invention commensurate in scope with the claims without undue experimentation."

Applicant's arguments have been fully considered but are not found persuasive.

Please note that Applicant did not amend the specification as suggested so that

"treating" does not encompass prevention, termination, cure, stoppage, etc. Amended

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claim 17 still encompasses the term "treating" as broadly defined by the specification (please see **35 USC § 112 – 1st Paragraph** below).

RESPONSE TO AMENDMENTS

Claim Rejections - 35 USC § 112 – 1st Paragraph

Claims 17-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for ameliorating ovarian cell cancer by administering cisplatin and TK-211, does not reasonably provide enablement for treating (as broadly defined in specification).

Although the Applicant has amended the claims as suggested by the Examiner, the term treatment is still broadly defined in the specification.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant claims a method of treating ovarian cancer in a patient, said method comprising: administering to said patient an amount of a cisplatin effective to treat said cancer in conjunction with an amount of TK-211 effective to reduce toxicity of said cisplatin. However, Applicant broadly defines "treatment" in paragraph 44:

[0044] "By treatment is meant that at least an amelioration of the symptoms associated with the condition afflicting the host is achieved, where amelioration is used in a broad sense to refer to at least a reduction in the magnitude of a parameter, e.g. symptom, associated with the condition being treated. As such, treatment also includes situations where the pathological condition, or at least symptoms associated therewith, are completely **inhibited**, e.g., **prevented** from happening, or **stopped**, e.g. **terminated**, such that the host no longer suffers from the condition, or at least the symptoms that characterize the condition."
(emphasis added)

The test of enablement requires a determination of whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. That standard is still the one to be applied. In *re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term “undue experimentation,” it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In *re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Scope of the claims. The claims are broad and read on a method to prevent, inhibit or terminate ovarian cancer. The term, “treatment”, as defined in the specification is too broad and is exacerbated by encompassing functions that are not considered possible today in the art of cancer treatment.

State of the art. The art in the field of cancer treatment has not developed to the level in which pharmaceuticals can prevent, inhibit or terminate the cancer. In 2002 Shazib Pervaiz (Curr Pharm Des. 2002;8(19):1723-34.) asks, “Are we close to making the turn from treating to curing cancer?”. Suggesting that there is no way yet to prevent, inhibit or terminate cancer. Colombo et al. (*Journal of Clinical Oncology*, Vol 25, No 20 (July 10), 2007: pp. 2944-2951.) discloses that the response rate to cisplatin treatment is not inhibited, terminated or prevented.

Relative skill of those in the art. The relative skill of those in the art of pharmaceuticals is high.

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The breadth of the claims. The breadth of the claims is further exacerbated by encompassing functions that are not considered possible today in the art of cancer treatment.

The presence or absence of working examples. As stated above, the specification only provides the usefulness of reducing the toxicity of cisplatin by administering cisplatin in combination with TK-211 for ovarian cancer treatment. The specification fails to provide adequate representation regarding treating all cellular proliferative diseases.

The quantity of experimentation necessary. The prevention, inhibition, or the termination of all ovarian cancer using a combination of cisplatin and TK-211 cannot be predicted a priori but must be determined from painstaking experimental study. When the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to use the invention commensurate in scope with the claims.

Given the analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be concluded that the skilled artisan would have to conduct undue and excess experimentation in order to practice the claimed invention.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Chris Simmons
Patent Examiner
AU 1614

October 9, 2007



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

JDA